

Technical Information

Diluting Fluid D

Product Code: DM 2686

Application: - Diluting Fluid D is recommended for sterility testing of pharmaceuticals in accordance with USP, 2011.

Composition**

Ingredients	Gms / Litre
Peptic digest of animal tissue	1.000
Polysorbate 80	1.000
Final pH (at 25°C)	7.1±0.2

**Formula adjusted, standardized to suit performance parameters

Principle & Interpretation

Diluting Fluid D is recommended as rinsing fluid for membrane filter method used in validation tests for bacteriostasis and fungistasis activity of pharmaceutical articles before carrying out sterility test procedures as per USP (1). After filtering the specified quantity of the test specimen, the membrane is rinsed with measured portions of rinsing or diluting fluid. This rinse is inoculated with known number of test bacteria and fungi as specified in pharmacopoeia. The resultant growth is compared with positive control to determine presence of fungistasis or bacteriostasis activity in test specimen. This medium is recommended for articles containing lecithin or oil or for devices labeled as sterile pathway (1).

Methodology

Suspend 2.0 grams of dehydrated media in 1000 ml distilled water. Mix thoroughly & heat if necessary to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes i.e. validated cycle.

Quality Control

Appearance

Cream to yellow coloured homogeneous free flowing powder

Colour and Clarity

Light amber coloured clear solution without any precipitate

Reaction

Reaction of 0.2% w/v aqueous solution at 25°C. pH : 7.1±0.2

pH Range

6.90-7.30

Cultural Response

DM 2686: Cultural characteristics observed after an incubation at 35-37°C for 24-48 hours.

Organism	Inoculum (CFU)	Growth
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Cultural Response

<i>Candida albicans</i> ATCC 10231	50-100	good
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<i>Escherichia coli</i> ATCC 25922	50-100	good
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<i>Staphylococcus aureus</i> ATCC 25923	50-100	good
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Dehydrated Culture Media
Bases / Media Supplements

<i>Escherichia coli</i> ATCC 8739	50-100	good
<i>Staphylococcus aureus</i> ATCC 6538	50-100	good

Storage and Shelf Life

Dried Media: Store below 30°C in tightly closed container and the prepared medium between 2 – 8°C. Use before expiry date on the label.
Prepared Media: 2-8° in sealable plastic bags for 2-5 days.

Further Reading

1. The United States Pharmacopoeia / National Formulary, USP34 / NF29, 2011, The US Pharmacopeia convention Inc., Rockville, MD.

Disclaimer :

- User must ensure suitability of the product(s) in their application prior to use.
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